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4. TITLE AND SUBTITLE

CENTERINGPREGNANCY© (CP): A Longitudinal Correlational Study Designed to Evaluate Maternal and Fetal Outcomes After Participation in CP

5a. CONTRACT NUMBER

FWH20080072H

5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

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10. SPONSOR/MONITOR'S ACRONYM(S)

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12. DISTRIBUTION/AVAILABILITY STATEMENT

DISTRIBUTION A. Approved for public release: distribution unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

Purpose: Of this study is to assess the feasibility, patient acceptance, military and social benefits and birth outcomes associated with the Centering pregnancy model prenatal care compared to traditional obstetric care. A statistical power calculation estimates that approximately 650 subjects will be required in each group in order to make the necessary comparisons and accurately assess the potential benefits of the Centering Pregnancy model. This study seeks to make a randomized assessment attempting to decrease selection bias to enrollment and to evaluate social support as a possible explanation for reducing maternal stress and thereby improving fetal outcomes. The free access to quality traditional obstetric care but the transient nature of the DoD population and the frequency of deployments make the military population ideally situated to assess the benefits of CP and take advantage of this method of prenatal care if proven superior to traditional care.

Significance: Findings from this study may aid in changing the routine prenatal care paradigm which generally involves brief

15. SUBJECT TERMS

Centering Pregnancy

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			M. Bardett Fausett, Col, USAF, MC
U	U	U	UU		19b. TELEPHONE NUMBER *(Include area code)* 210-292-6100

WHASC – Non-Exempt Human Research
Final Report

1. Protocol Number: FWH20080072H **IRBNet#** 379048-2

2. Title:

CENTERINGPREGNANCY© (CP): A LONGITUDINAL CORRELATIONAL STUDY DESIGNED TO EVALUATE MATERNAL AND FETAL OUTCOMES AFTER PARTICIPATION IN CP

3. Principal Investigator (PI): WHASC PI: Co-PI: (state organization)

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Rank	Col	
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4. Purpose:

The purpose of this study is to randomly assess the feasibility, patient acceptance, social benefits, and birth outcomes associated with the CenteringPregnancy (CP) model of prenatal care compared to traditional obstetric care. Both methods of prenatal care are commonly used in the US and are used here at WHMC. The primary birth outcomes assessed will be birth weight and gestational age at delivery.

5. Results:

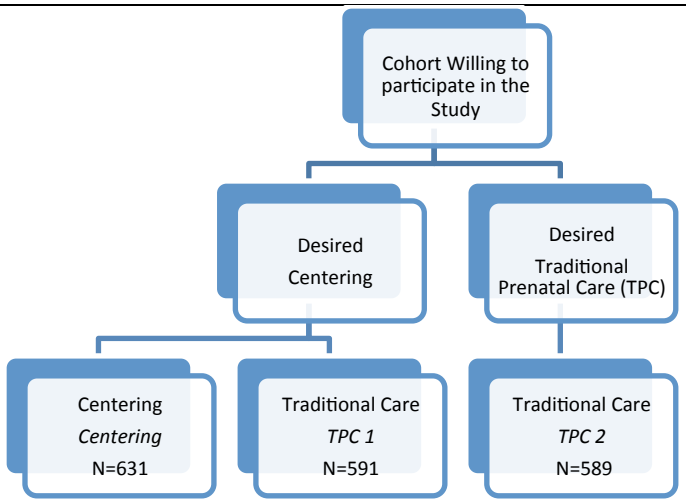
Summarize the findings of your study. Include results as they relate to each of your research questions/hypotheses.

Compared to traditional individual care, group prenatal care has shown promise as a method of primary prevention of PTD. Several retrospective, and one randomized study of Group prenatal care, suggest risk reductions of 33 to 60% compared to traditional care. CenteringPregnancy® (herafter called Centering) is the most studied method of group prenatal care. In the Centering method, 8-12 women of similar gestational age receive their prenatal care during two hour visits occurring at typical intervals in a group setting. Sessions include routine prenatal assessments, facilitated discussions, group education and social activities. These activities and discussions promote group bonding. Patient and provider satisfaction rates are very high with this method of care and long-term friendships are common.

We designed a randomized study to assess the effectiveness of group prenatal care to reduce the risk of preterm birth compared to standardized evidence-based individual prenatal care. We also sought to evaluate the impact mediated by subject's perception of social support, stress, anxiety, depression and sense of control.

With IRB approval we began enrollment in March 2009 and the last subject delivered in September 2011. The setting was two Texas military hospitals. The study sites and providers were certified in the CenteringPregnancy™ method. The providers facilitating Centering groups included midwives, women's health nurse practitioners, and general OB/GYN and MFM physicians.

Subjects were recruited from obstetric orientation and genetic counseling classes. During the study period, Centering was only available to women agreeing to participate in the study. Women who were willing to participate in the study selected their preferred method of prenatal care. Those women favoring Centering were contacted by telephone and their willingness to participate re-verified. Using a random number table, a portion of these women were randomized to receive either Centering or Traditional Prenatal care here designated as Centering and TPC 1. A second control group, designated as TPC 2 was composed by randomly sampling a contemporary portion of women desiring Traditional care but willing to participate in the other aspects of study. The two control groups were established to evaluate different kinds of potential bias. The women in the study and control groups were asked to complete surveys 3 times during their pregnancy. 9 Subjects w/ incomplete outcomes were excluded.



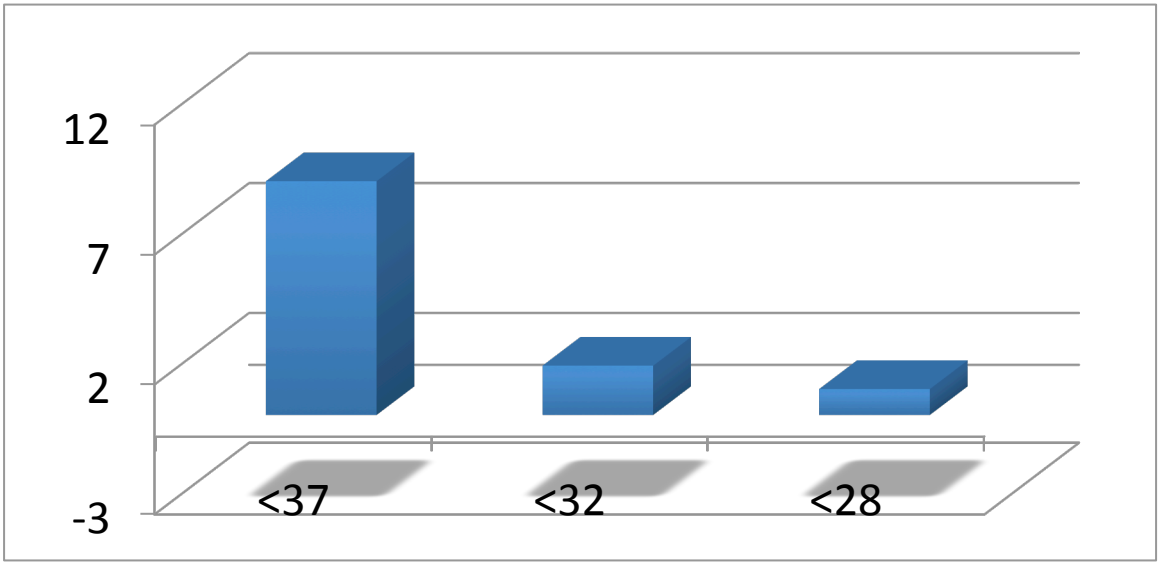
The demographics of the study population.

Race	% of Population
White/Caucasian	61.0
Black/African American	16.4
Other (mostly white Hispanic)	17.1
Asian or Pacific Islander	4.1
Native American	1.3

Despite our attempt at randomization, more African American women ended up in the Centering group versus the combined control group. The 22 vs 14%. Centering and the individual control groups were effectively randomized with regard to the numbers of pre-existing medical conditions, multiple gestations and prior preterm deliveries.

All of the subjects in the study were asked to complete validated surveys at 3 times during their pregnancies. The surveys included questions related to stress, anxiety, depression and sense of control as well as various support mechanisms. Our analysis of the surveys included an assessment of multiple individual questions, composite scores and changes in scores between the first and second surveys. We were unable to identify any differences in survey scores in Centering versus controls that related to the risk of early PTD prevention.

The incidences of Preterm delivery less than 37, 32 and 28 weeks from the entire study population are shown below. The overall Preterm Delivery rate <37 weeks in this population was significantly lower than the overall US population during this time frame.



Average US Population PTD <37 wks during study was 11.6%.

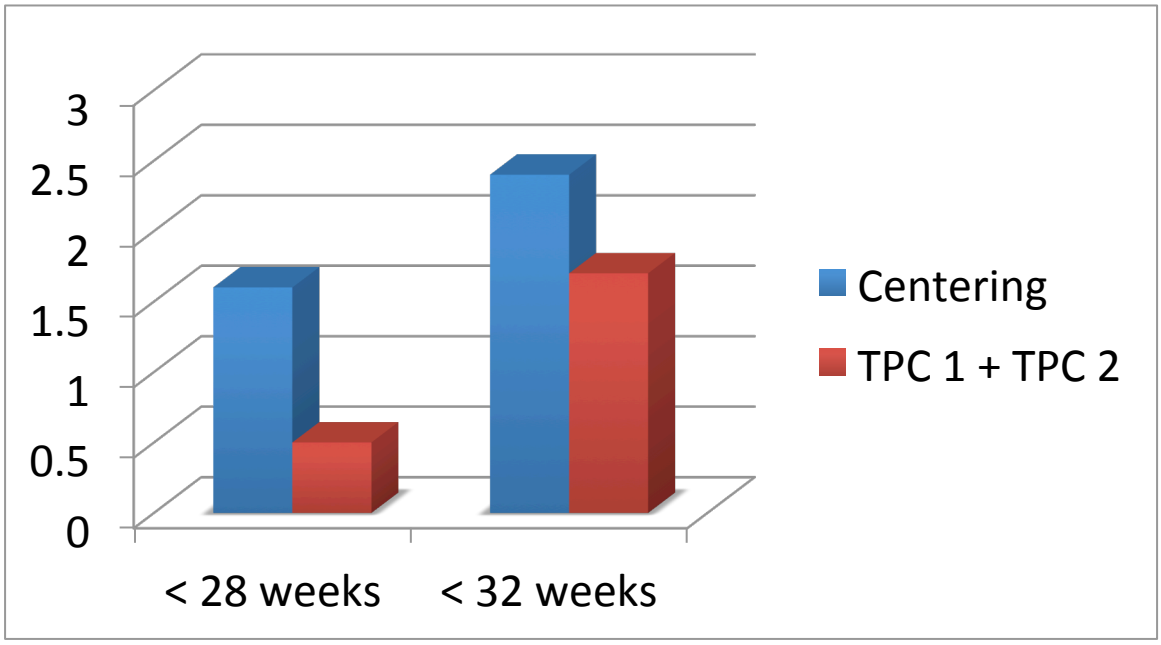
The racial disparity of PTD identified in the general US population was also present in our study population despite our standardized prenatal care and the normalization of socio-economic circumstances that occurs in the military. The PTD rate for African Americans was 14.9% versus 8.8% for Caucasians. The associated frequency distribution of viable deliveries is graphically represented in the blue box. The PTD rate for women in other Ethnic groups were not statistically different from the White/Caucasian population.

We did not detect a difference in the rates of PTD <37 weeks between the study and either control group individually or, the control groups combined.

Comparisons	P Values
Centering vs TPC 1	0.71

Centering vs TPC 2	0.99
Centering vs TPC 1 + TPC 2	0.82

When we compared the Centering Group to the TPC 1 Control Group, the Centering group had fewer PTD in both the <32 and <28 week categories.



In bivariate models that included race and method of care, race was independently associated with risk of PTD in the <37, <32 and <28 week PTD groups. All have p values less than 0.01. On the other hand, Method of Care did not achieve independent statistical significance in any of the three PTD groups though the Relative Risks and P values in the table suggest there might be a trend.

	RR	**95% Confidence**
< 37 weeks	0.94	(0.60 – 1.48)

< 32 weeks	0.58	(0.21 – 1.59)	0.29
< 28 weeks	0.14	(0.15 – 1.18)	0.07

We found predictive modeling of this same bivariate analyses to be quite informative. Looking at the columns, note that in each gestational age group, the racial disparity in the incidence of preterm delivery is present. Looking at the rows, note that Centering is associated with with fewer preterm deliveries in both racial groups and in each gestational age grouping.

Predictive Modeling

Delivered < 37 Weeks (%)

	Centering	TPC 1
African-American	14.9	15.7
Caucasian	7.1	7.6

Delivered < 32 Weeks (%)

	Centering	TPC 1
African-American	3.3	5.6
Caucasian	0.7	1.2

Delivered < 28 Weeks (%)

	Centering	TPC 1
African-American	0.6	4.0
Caucasian	0.1	0.5

When we add the % risk reduction in a third column, it becomes more apparent that the beneficial effect of Centering on the risk of PTD increases dramatically at earlier gestational ages yet, the magnitude of the effect is very similar between the races in each gestational age group.

Predictive Modeling

Delivered < 37 Weeks (%)

	Group Care	Traditional Care	Risk Reduction (%)
African-American	14.9	15.7	**5**
Caucasian	7.1	7.6	**7**

Delivered < 32 Weeks (%)

	Group Care	Traditional Care	Risk Reduction (%)
African-American	3.3	5.6	**41**
Caucasian	0.7	1.2	**42**

Delivered < 28 Weeks (%)

	Group Care	Traditional Care	Risk Reduction (%)
African-American	0.6	4.0	**85**
Caucasian	0.1	0.5	**80**

We believe that the biggest weakness of the study is our failure to maintain randomization of the African American subjects. This, in combination with our lower than typical preterm birth rate, resulted in our study being underpowered to detect clinically significant differences in the PTD rate less than 37 weeks.
Never-the-less, as far as we are aware this is the largest and only the second randomized trial on this subject. Our two control group design did allowed us to control for different kinds of bias. The randomization worked well enough to evenly distribute women with known increased risks of PTD within the groups. Our ethnically diverse population reflects the general US population. Taken together these make our findings reasonably generalizable.
We also believe that the evidence based prenatal care Guideline applied to all our military patients decreases the probability that previously reported differences between Group and Traditional care were simply a reflection of good versus bad or good versus better prenatal care. Finally, the frequent disruption of social support groups in the military augmented our ability to assess the potential benefit of group support and bonding on reducing the risk of PTD. We did a comprehensive assessment of the impact of stress, depression, anxiety, sense of loss of control and varied support mechanisms.

Our conclusions. First, compared to our Traditional method of care, Group prenatal care has no detectable impact on the rate of PTD <37 weeks. However, group prenatal care does reduce the risk of early preterm delivery. The magnitude of the effect seems to be inversely correlated with gestational age. We also conclude that while the ability of Centering to reduce the risk of preterm delivery is more easily detectable in African American women, the magnitude of the effect is probably not race related. Finally, we were surprised to find that the mechanism by which group prenatal care reduces the risk of early PTD does not appear to be related to Stress, Anxiety, Sense of Control or Depression Scores or perceived support mechanisms.

The mechanism by which group prenatal care reduces the risk of early PTD warrants further study. Finally, CenteringPregnancy is the method of group prenatal care that has been most studied. Future studies should include RCTs comparing Centering with other methods of Group prenatal care.

6. How may your findings benefit the Air Force?

Despite perceptions about the medical care provided in the AF and the military in general, an obstetric indication is the most common reason for admission to an AF Hospital. Preterm deliveries result in millions of dollars of cost of care annually in the DoD, the average preterm delivery costs the DoD approximately 70K/patient. The long term health costs are also extremely large due to the chronic disease related complications of preterm birth. There are approximately 100,000 military beneficiaries who deliver each year. Thus, any improvement in the outcomes, particularly the incidence of preterm birth amongst the obstetric population could have a profound financial, and readiness impact on the AFMS and the entire DoD.

7. Total Number of Subjects Entered into the Study:

	Projected number at beginning of study	**Total actually enrolled**
Number of subjects enrolled at WHASC	942	942
Number of subjects enrolled at CRDMC	942	942

7.1 Consent Process:

Each participant was recruited in accordance with the recruitment plan approved by the IRB. [X] Yes [] No
Each participant was consented in accordance with the consent process approved by the IRB. [X] Yes [] No
Each participant was given a copy of the signed, dated informed consent document. [X] Yes [] No
As the PI, I have retained a copy of each participant's signed, dated informed consent document. [X] Yes [] No

8. Status of Subjects:

The subjects' experiences and involvement in the study were as anticipated. No adverse outcomes occurred as a result of participation in the study.

The study has the potential for long term side effects: [ ] Yes [X] No

The study implanted a device into the subject: [ ] Yes [X] No

9. Reason for Closure: Objectives of the study were met

10. Problems: None

10.1 Summary of an Unanticipated Problem Involving Risk to Subjects or Others (UPIRSO) Event: NONE.

10.2 Summary of a Serious Adverse Event (SAE): NONE.
Since Last Report

10.3 Summary of a Protocol Deviation Event: NONE.

10.4 Summary of Withdrawals from the Study:

For the Entire Study

Date of Withdrawal	**Withdrawals Due to Screening Failure**	**Reason for Patient Withdrawal**
WHMC		
Jul 09		PCS
Sep 09		PCS
Oct 09		PCS
Nov 09		Transfer to civilian care
Jan 10		PCS to Hawaii, dependent daughter
Jan 10		PCS
Jan 10		Separated from Air Force; to civilian care
Feb 10		PCS
May 10		Transfer out of state to civilian care
Jun 10		PCS
Jun 10		PCS
Oct 10		Transfer to civilian care
May 12	Minor at time of consent	

May 12	Minor at time of consent	
May 12	Minor at time of consent	
May 12		Moved, unable to contact for outcomes
May 12		Preterm delivery at 17 weeks
May 12		IUFD at 20 weeks
CRDAMC		
Dec 09		SAB
Feb 10		Transfer to civ care- subject request, dependent daughter
Feb 10		Transfer to civ care- subject request, no further care at MTF
Apr 10		ETS- no further care at MTF
Apr 10		Sponsor medically retired, moved out of state
May 10		Sponsor ETS, no longer eligible for care
May 10		Sponsor ETS, no longer eligible for care
May 10		Sponsor chaptered out, no longer eligible for care
Jun 10		Sponsor ETS, no longer eligible for care
Jun 10		Sponsor ETS, no longer eligible for care
Jun 10		Sponsor ETS, no longer eligible for care
Jul 10		Transfer to civ care, fetal indications, dependent daughter
Jul 10		Dep daughter, withdrew from school, no longer eligible
Jul 10		Delivered in Florida, no further care at MTF
Aug 10		Moved to MO, no further care at MTF
Sep 10		ETS- no longer eligible for care
Sep 10		Moved to San Angelo, no further care at MTF
Sep 10		Sponsor ETS, no longer eligible for care
Sep 10		Sponsor ETS, no longer eligible for care
Sep 10		Sponsor chaptered out, no longer eligible for care
Sep 10		Sponsor ETS, no longer eligible for care
Sep 10		Sponsor chaptered out, no longer eligible for care
Oct 10		PCS to Hawaii, no further care at MTF
Oct 10		Transfer to civ care, subject request, no further care at MTF
Nov 10		ETS, no longer eligible for care
May 12	Minor at time of consent	
May 12	Minor at time of consent	
May 12	Minor at time of consent	
May 12	Minor at time of consent	
May 12		Pregnancy terminated
May 12		Moved, unable to contact for outcomes
May 12		Moved, unable to contact for outcomes
May 12		IUFD at 16 weeks
May 12		IUFD at 17 weeks
May 12		IUFD
May 12		IUFD at 18 weeks
May 12		Moved, unable to contact for outcomes

10.5 Complaints about the Study: NONE.

10.6 Other Problems: NONE.

11. Status of Resources:

Funding from the Surgeon General Office (SGO) in the amount of $27,000 was approves in my original protocol. That money has been spent by the closing of fiscal year 2013. I have obtained ongoing funding for the research personnel support from a different source of SGR funding via the OB/GYN consultant to the AF/SG

I have received External Resources to support this study in the form of:

(1) From March of Dimes to WHMC CenteringPregnancy Program.

$5,000 from year 2007; $5,000 for year 2008
(2) From March of Dimes to Carl R. Darnall Army Medical Center CenteringPregancy Program
$5,000 for year 2007; $5,000 for year 2008; $5,000 for year 2009; $5,000 for year 2010; $12,000 for 2011

The study used a drug that had an IND: **[ ] Yes** **[X] No**

The study used a device that had an IDE: **[ ] Yes** **[X] No**

12. Describe the local investigator's ongoing plan to protect the confidentiality of the research data:

All research files have been de-identified.

12.1 Describe the local investigator's plan to store the research records:

Signed ICDs and HIPAA forms will be kept secured for three years after closure of the study. Then they will be shredded.

13. Publications and Presentations:

For the Entire Study

Date	Authors	Title
5 Feb 14 Oral Presentation at the Society for Maternal Fetal Medicine Annual Clinical Meeting.	M. Bardett Fausett, Col Nicholas Teneyuque, CPT Barton Staat, Lt Col And Andrea Shields, Lt Col	Centering Pregnancy is associated with reduced preterm birth in the African American population but not overall.

These Presentations and publications have been cleared by CI and Public Affairs. [X] Yes [ ] No

14. Exceptional Achievements:

CenteringPregnancy is continually offered as a platform of obstetric care at SAMMC, WHASC and CRDAMC. These findings and the implementation should occur through out the DoD and apply to the delivery of prenatal care through out the world.

15. Signature of Principal Investigator:

PI's Signature Block or PI's Provider Stamp

Date: 21 Apr 14

M. Bardett Fausett, Col, USAF, MC
AF/SG Consultant for OB and MFM
Chief, OB/GYN and Women's Health, WHASC